COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 09.03.1998
COM(1998) 160 final

Proposal for a

COUNCIL DECISION

on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies and repealing Decision 97/534/EC

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. The decision replaces Commission Decision 97/534/EC laying down the rules on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies (SRM). It amends its provisions in respect of the following points :

- The list of SRM is enlarged in accordance with the opinion of the Scientific Steering Committee (SSC) of 9 December 1997. This list will apply as from 1 July 1998.

- The Decision allows Member States and Third countries with regard to their exports to the Community to ask for a total or partial derogation from the SRM ban in the light of their geographical risk. The following procedure applies :
Member States requesting a derogation must submit the data necessary to allow assessment of their geographical BSE risk until 30 June 1998 at the latest. For these Member States, the entry into force of the enlarged Community SRM list will be suspended until 31 December 1998 in order to allow for the scientific assessment and the subsequent decision making. However, Member States with BSE cases in their cattle population have to apply SRM removal rules on the basis of a shorter list. However this list cannot be shorter than the list recommended by the Office international des Epizooties (OIE) in 1997.

Third countries will also be invited to submit the necessary data in the same time scale. Imports from third countries, which have followed this invitation (except Switzerland which has native BSE cases), will be exempted from the requirement of SRM removal until 31 December 1998. For imports from Switzerland the 1997 OIE list of SRM will apply until this date.

- An exemption for Member States applying a compulsory single carcass test for bovines above a certain age is introduced in the Decision. As a precondition such tests must be approved by the Commission after validation will have been carried

out. A derogation for relevant products derived from tested carcasses to be imported from third countries is also foreseen.

- A derogation for the use of SRM in certain products covered by sectoral legislation, e.g. medicinal and cosmetic products, and industrial products is foreseen.

2. This decision is in accordance with the advice given by the SSC on 9 December 1997 and improves consumer safety while avoiding unjustified trade, economic and technical consequences. In addition it allows for taking into account future scientific advice and for respecting WTO notification requirements.

3. This decision will be combined with the reinforced implementation of existing measures for minimising the BSE risk and improved surveillance (see separate draft decision on epidemio-surveillance for TSE and amending Decision 94/474/EC).

In the Standing Veterinary Committee meeting of 4 March Greece, Spain and Sweden supported the proposal. The Netherlands voted against the proposal because they feel TSEs are diseases for which regionalisation is impossible in principle. The United Kingdom, France, Luxembourg, Portugal and Belgium are against regionalisation before the criteria have been harmonised, but could accept regionalisation in future. Belgium, Denmark, Germany, Ireland, Italy, Austria and Finland are against the proposal because of the enlarged list of SRMs, which they consider unscientific and which would automatically come into force on 1 January 1999, in the absence of a Commission decision.

The Commission not having received a favourable opinion from the Standing Veterinary Committee, is required under Article 17 of Directive 89/662 to submit a porposal to the Council without delay.

PROPOSAL for a

COUNCIL DECISION

of

on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies and repealing Decision 97/534/EC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market[1], as last amended by Directive 92/118/EEC[2], and in particular Article 9 (4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market[3], as last amended by Directive 92/118/EEC, and in particular Article 10(4) thereof,

Having regard to Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries[4], as last amended by Directive 96/43/EC[5], and in particular Article 19 thereof,

Having regard the proposal of the Commission,

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[1] OJ No L 395, 30.12.1989, p.13.
[2] OJ No L 62, 15.3.1993, p. 49.
[3] OJ No L 224, 18.8.1990, p. 29.
[4] OJ No L 373, 31.12.1990, p. 1.
[5] OJ No L 162, 1.7.1996, p. 1.

(1) Whereas under Directive 89/662/EEC and Directive 90/425/EEC, the Member State of origin or dispatch is required to implement on its territory the appropriate measures to prevent all situations likely to constitute a serious hazard to animals or to human health;

(2) Whereas new information has been published in the United Kingdom further supporting the hypothesis that exposure to the bovine spongiform encephalopathy (BSE) agent is linked to the new variant of Creutzfeldt Jacob Disease (CJD) in humans; whereas on 16 September 1997 the Spongiform Encephalopathy Advisory Committee (SEAC) of the United Kingdom concluded that recent research provided compelling new evidence that the agent which causes BSE is identical to the agent which causes the new variant of CJD in humans; whereas on 18 September 1997 the Advisory Committee on Dangerous Pathogens (ACDP) concluded that the BSE agent should now be classified as a human pathogen;

(3) Whereas Commission Decision 94/381/EC of 27 June 1994 concerning certain protection measures with regard to bovine spongiform encephalopathy and the feeding of mammalian derived protein[6], as amended by Decision 95/60/EC[7], prohibited the feeding of mammalian protein to ruminants throughout the Community;

(4) Whereas Commission Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy[8], as amended by Decision 96/362/EC[9], was adopted pending further evaluation of the new information and further measures to protect animal and public health;

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[6] OJ No L 172, 7.7.1994, p. 23.
[7] OJ No L 55, 11.3.1995, p. 43.
[8] OJ No L 78, 28.3.1996, p. 47.
[9] OJ No L 139, 12.6.1996, p. 17.

(5) Whereas Commission Decision 96/449/EC of 18 July 1996 on the approval of alternative heat treatment systems for processing animal waste with a view to the inactivation of spongiform encephalopathy agents[10], lays down the best available method for processing animal waste as regards spongiform encephalopathy agents;

(6) Whereas a group of experts convened by WHO on 3 April 1996 recommended that no part or product of any animal which had shown signs of a transmissible spongiform encephalopathy (TSE) should enter any food chain (human or animal), and that countries should not permit tissues that are likely to contain the BSE agent to enter any food chain (human or animal); whereas the Scientific Veterinary Committee has assessed the measures needed in the whole Community in order to put the recommendations of that group of experts into effect;

(7) Whereas the Scientific Veterinary Committee has concluded on the basis of its risk assessment that the rendering procedure using 133 °C at 3 bar for 20 minutes is the most important factor to assure the safety of meat-and-bone meal, but that this system cannot completely guarantee the complete removal of a TSE agent present in the material to be rendered if the system is challenged with material with high infectivity;

(8) Whereas the Scientific Veterinary Committee in its opinion of 21 October 1996 recommended on the basis of its risk assessment that specified risk materials, defined as brain, spinal cord and eyes from cattle, sheep and goats over one year of age and spleens from sheep and goats over six months of age, should be removed from all food and feed chains in countries or regions where a potential risk is identified, and that, in the case of fallen cattle, sheep and goats, either the specified risk materials should be removed so that they do not enter any food or feed chain, or the whole carcase should be destroyed;

[10] OJ No L 184, 24.7.1996, p. 43.

(9) Whereas on the basis of the advice of the Scientific Veterinary Committee of 21 October 1996, in accordance with the risk assessment carried out by that Committee, the Commission adopted Decision 97/534/EC of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies[11], as amended by Decision 97/866/EC[12];

(10) Whereas the Scientific Steering Committee (SSC) adopted an opinion on 9 December 1997; whereas in this opinion the SSC suggested a new and enlarged list of specified risk materials and proposed that those materials should be excluded temporarily from human and animal consumption depending on the geographical source;

(11) Whereas in the light of the new scientific advice it is necessary to amend the list of specific risk materials laid down in Decision 97/534/EC; whereas this list should apply as from 1 July 1998; whereas Member States and third countries in so far as concerns their exports to the Community should be allowed to ask for a total or partial derogation from the ban on specified risk materials in the light of their geographical risk; whereas it is necessary to establish a procedure for submission of the data necessary to allow assessment of the geographical BSE risk; whereas pending such scientific assessment and the subsequent decision on the matter, the application of the enlarged list of specified risk materials should be suspended until a date not later than 31 December 1998; whereas, however, Member States and third countries with BSE cases in their bovine animal population and currently applying the removal of risk materials should at least remove the materials recommended by the World Organisation for Animal Health (Office international des Epizooties; OIE) in 1997;

[11] OJ N° L 216, 8.8.1997, p.95.
[12] OJ L 351, 23.12.1997, p. 69.

(12) Whereas Article 3.2.13.12 of the Animal Health Code of the OIE recommends that bovine brain, eyes, spinal cord, tonsils, thymus, spleen and distal ileum (tissues under study) and protein products derived from them from cattle over six months of age originating from countries with a high incidence of BSE should not be traded between countries; whereas that Code recommends in the same Article that bovine brain, eyes, spinal cord and distal ileum (tissues under study) and protein products derived from them from cattle over six months of age, originating from countries with a low incidence of BSE, which were born before the feed ban was effectively enforced should not be traded between countries;

(13) Whereas it is necessary for practical and precautionary reasons to exclude the use of spleens from ovine and caprine animals, irrespective of age, and mechanically recovered meat from the vertebral column of bovine, ovine and caprine animals;

(14) Whereas measures must be implemented in order to protect ruminants from scrapie pending a proper epidemiological evaluation of the situation in the Community;

(15) Whereas certain Member States have already excluded certain material from the food and feed chains; whereas the United Kingdom has prohibited tissues in addition to those recommended by the Scientific Veterinary Committee;

(16) Whereas the United Kingdom is considered to be a country with a high incidence of BSE; whereas the tissues included on the list of specified bovine materials of the United Kingdom are in conformity with the list of the aforementioned Article of the Animal Health Code; whereas, therefore, the United Kingdom should be authorized to keep the existing national measures in respect of the removal of specified bovine material in force;

(17) Whereas a risk assessment based on accepted scientific methodology may show that there is a significantly higher risk of exposure of animals or humans to TSEs in certain Member States; whereas those Member States may take action in respect of the removal of additional risk material from animals slaughtered on their territory;

(18) Whereas equivalent guarantees are required for imports from third countries; whereas the situation as regards TSEs may vary between countries and the import requirements may therefore be adapted to the particular situation of the countries of origin or dispatch; whereas the import of specified risk materials should be allowed only for the purposes for which their use in the Community is permitted;

(19) Whereas the 20th Commission Directive 97/1/EC of 10 January 1997 adapting to technical progress Annexes II, III, VI and VII of Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products[13] bans provisionally the marketing of cosmetic products containing bovine, ovine and caprine tissues and fluids from the encephalon, the spinal cord and the eyes, and the ingredients derived therefrom; whereas that Directive is being amended to take account of the provisions of Decision 97/534/EC;

(20) Whereas the marketing of medicinal products in the Community is regulated by Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products[14], as last amended by Directive 93/39/EEC[15], and by Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products[16], as last amended by Directive 93/40/EEC[17]; whereas these Directives

[13] OJ No L 16, 18.1.1997, p. 85.
[14] OJ No L 147, 9.6.1975, p. 1.
[15] OJ L 214, 24.8.1993, p. 22.
[16] OJ No L 317, 6.11.1981, p. 16.

are being amended to take account of the provisions of Decision 97/534/EC;

(21) Whereas the amendments to Directives 97/1/EC, 75/318/EEC and 81/852/EEC provide for the protection of public health in respect of the use of specified risk material in cosmetic and medicinal products placed on the market in the Community; whereas, therefore, the regulation of these products may be excluded from the scope of this Decision; whereas, however, there remains a need to allow for derogations for the production of medicinal products and medical devices, their starting materials or intermediate products, in those cases where the competent authority has determined that no satisfactory alternative exists; whereas the operation of any such derogation will be regulated by Community rules laid down elsewhere;

(22) Whereas for in vitro diagnostic medical devices the use of SRM should remain possible where necessary for the correct performance of such products; whereas conditions of use of specified risk materials including related time schedules should be laid down in this Decision for medical devices within the meaning of Council Directive 90/385/EEC[18], as last amended by Directive 93/68/EEC[19], and Council Directive 93/42/EEC[20]; whereas those conditions should not apply to in vitro medical devices;

(23) Whereas the measures provided for in this Decision will further contribute to the safe sourcing, processing and use of ruminant material for food, feed, medicinal products, medical devices and cosmetic products;

(24) Whereas there are no effective controls or tests which can determine whether or not particular tissues have been used in the manufacturing of products;; whereas, therefore; those tissues should be removed at slaughterhouses and subsequently destroyed; whereas Member States should also be authorised to permit their

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[17] OJ L 214, 24.8.1993, p. 31.
[18] OJ No L 189, 20.7.1990, p. 17.
[19] OJ L 220, 30.8.1993, p. 1
[20] OJ L 169, 12.7.1993, p.1.

removal at cutting plants, high-risk processing plants or premises referred to in Article 7 of Council Directive 90/667/EEC[21], as last amended by Directive 92/118/EEC, and, as regards vertebral columns, at the point of sale to the consumer;

(25) Whereas it is appropriate to provide for derogations to permit the use of materials covered by this Decision for teaching and research purposes, for the production of products for purposes other than human food, animal feed, medicinal products or cosmetic products and for feeding fur animals, in addition to the derogations referred to above in respect of medicinal products, medical devices and cosmetic products;

(26) Whereas inspections were carried out in the Member States in 1996 and 1997 to check the implementation of Community measures on BSE; whereas the results of those inspections have revealed certain deficiencies, in particular in surveillance and implementation of the prohibition on use of mammalian protein in ruminant feed; whereas further inspections are necessary;

(27) Whereas in view of previous trade in certain products, in particular meat and bone meal and live animals, the possible presence of TSE agents cannot be ruled out in any of the Member States; whereas further scientific evaluation is necessary before a final assessment of the regional risk of the presence of TSE agents can be made;

(28) Whereas this Decision will be reviewed in the light of new scientific information with regard to risk of exposure to TSEs resulting from infectivity in other animal species, age categories, tissues or materials not covered by this Decision;

(29) Whereas the possibility exists that post-mortem tests for BSE may be developed and validated; whereas it is appropriate to provide for the approval of such tests to lay down rules for their use; whereas provision should be made

[21] OJ N°L363, 27.12.1990, p.51

for an exemption for Member States applying a compulsory single carcass test for bovine animals above a certain age;

(30) Whereas scientific investigations have indicated that stunning or killing by means of a gas injected into the cranial cavity and pithing may result in fragments of brain tissue entering the circulation and lodging in certain organs; whereas this could present a risk to consumers of those organs; whereas, therefore, those practices should be prohibited in areas where there is a risk from BSE;

(31) Whereas for reasons of transparency Decision 97/534/EC should be repealed and replaced by this Decision;

(32) Whereas the Standing Veterinary Committee has not given a favourable opinion,

HAS ADOPTED THIS DECISION:

Article 1

1. For the purposes of this Decision the following definitions shall apply:

(a) "specified risk material" shall mean:

(i) the skull, including the brain and dura mater, the pituitary gland, the eyes, the tonsils, the intestines from the duodenum to the rectum, the vertebral column, including the dorsal root ganglia, spinal cord and dura mater, of:

- bovine animals aged over 12 months,
- ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum;

(ii) the spleens of ovine and caprine animals;

(b) "native case of BSE" shall mean a case of BSE for which an epidemiological investigation conducted by the competent authority led to the conclusion that exposure of the affected animal to the agent took place within the territory of the country concerned;

(c) "pithing" shall mean the laceration after stunning of central nervous tissue by means of an elongated rodshaped instrument introduced into the cranial cavity.

2. Unless otherwise specified, any reference to "specified risk material" in this Decision is a reference to the tissues specified in paragraph 1 (a), not to products containing or derived from those tissues.

Article 2

1. Member States shall ensure that the following slaughter techniques are not used after 30 June 1998 on bovine, ovine and caprine animals whose meat is intended for human or animal consumption:

(a) stunning by means of a gas injected into the cranial cavity or killing by that method;

(b) pithing.

2. The use of the vertebral column of bovine, ovine and caprine animals for the production of mechanically recovered meat shall be prohibited after 30 June 1998. This shall not apply to animals which are subjected to a test in accordance with Article 6.

Article 3

1. Member States shall ensure that after 30 June 1998 the specified risk materials from animals which died or were slaughtered on their territory, are removed under the direct supervision of an official of the competent authority and are destroyed in accordance with Article 4.

2. The specified risk materials shall be removed at slaughterhouses.

3. By way of derogation from paragraph 2, Member States may allow the removal of:

(a) specified risk material at cutting plants, high risk processing plants or premises referred to in Article 7 of Directive 90/667/EEC. Those establishments shall be approved for that purpose by the competent authority;

(b) the vertebral column at the point of sale to the consumer on their territory.

4. The Commission may establish conditions, in particular with regard to checks, in accordance with the procedure laid down in Article 18 of Directive 89/662/EEC.

5. By way of derogation from paragraph 1, where bovine, ovine or caprine animals have died or have been killed in the context of disease control measures, their entire body may be destroyed by one of the methods referred to in Article 4 without removal of the specified risk materials.

Article 4

Specified risk material shall be stained with a dye immediately on removal. All specified risk material, including that obtained before 1 July 1998, shall be destroyed:

(a) by incineration; or,

(b) provided that the colour of the dye is detectable after processing, by processing followed by:

(i) incineration;

(ii) burning as fuel; or,

(iii) another method, which precludes all risk of transmission of a TSE, and is authorized and supervised by the competent authority.

Article 5

1. Member States may derogate from the provisions of Articles 3 and 4 to allow the burning or burial of specified risk material or entire bodies in the circumstances set out in Article 3(2) of Directive 90/667/EEC.

2. Member States may derogate from the provisions of Articles 3 and 4 to allow the use of specified risk material:

(a) for the purposes of teaching or research in officially recognized establishments;

(b) for feeding fur animals.

3. Member States may derogate from the provisions of Article 4 to allow the use of specified risk material:

(a) for the production of medicinal products, their starting materials or intermediate products subject to the provisions of Directives 75/318/EEC and 81/852/EEC;

(b) for the production of in-vitro diagnostic medical devices and of medical devices within the meaning of Directive 93/42/EEC which are not intended to come into direct contact with patients, including their starting materials or intermediate products;

(c) for the production of medical devices within the meaning of Directive 90/385/EEC and of Directive 93/42/EEC which are intended to come in direct contact with patients, including their starting materials or intermediate products; further conditions are laid down in Annex II;

(d) for the production of cosmetic products, their starting materials or intermediate products, subject to the provisions of Directive 76/768/EEC;

(e) for the production of products other than those referred to in points (a) to (d) which are not intended for use in human food, animal feed or fertilisers.

Article 6

1. Member States may authorise, as an alternative to the removal of specified risk materials provided for in Articles 3 and 12 or by way of derogation from the prohibition laid down in Article 2 (2), the application of a post-slaughter test which has been approved in accordance with Article 18 of Directive 89/662/EEC, provided that at least:

(a) tests are be carried out in the slaughterhouses on all bovine animals aged over 12 months, and as appropriate, on all ovine and caprine animals which are aged over 12 months or have a permanent incisor tooth erupted through the gum;

(b) the spleens of ovine and caprine animals are removed and destroyed in accordance with Article 4;

(c) no bovine, ovine or caprine material leaves the slaughterhouse before the results of the tests on all slaughtered animals produced in the same batch, that is after one process of cleaning and disinfection of the slaughterchain and before the next, have been received and accepted by the competent authority;

(d) when a post-slaughter test gives a positive result, all bovine, ovine and caprine material produced in the same batch after the last process of cleaning and disinfection of the slaughterchain is destroyed in accordance with Article 4.

2. With respect to products referred to in Annex III which may be imported into the Community, third countries may authorise as an alternative to the removal of specified risk materials, the application of a post-slaughter test which has been approved in accordance with this Decision, provided that at least the conditions set out in paragraph 1 are met.

Article 7

1. To ensure that this Decision is applied correctly, Member States shall carry out frequent official controls, particularly in slaughterhouses, cutting plants, animal waste processing plants, high risk processing plants or premises referred to in Article 7 of Directive 90/667/EEC, points of sale to the consumer and storage facilities, and shall take measures to avoid contamination.

2. Member States shall set up a system to ensure and check that:

(a) where derogations have been granted in accordance with Article 3 (3) for the removal of specified risk materials at establishments other than slaughterhouses, those materials are completely separated from other waste, are collected separately, and are destroyed in accordance with Article 4;

(b) specified risk materials for which derogations have been granted in accordance with Article 5 (2) and (3) are exclusively used for the authorised purpose;

(c) where live bovine, ovine or caprine animals originating from Member States or third countries in which native cases of BSE have occurred are received by Member States in which no native cases of BSE have occurred in accordance with Article 12 (3), those animals remain under official supervision until their slaughter or until dispatch from their territory.

Article 8

1. Without prejudice to Article 5 (2) and (3), the import into the Community of specified risk material shall be prohibited after 30 June 1998.

2. In order to be imported into the Community after 30 June 1998, products of animal origin listed in Annex III which contain material derived from bovine, ovine or caprine animals produced after 30 June 1998 and are intended for human food or animal feed must be accompanied by the appropriate certificate, as required by Community legislation, supplemented by a declaration signed by the competent authority of the country of production, worded as follows:

"The product does not contain, and is not derived from, specified risk material, as defined in Commission Decision [98/- - -/EC], which was produced after 30 June 1998 or mechanically recovered meat obtained from the vertebral column of bovine, ovine or caprine animals after 30 June 1998."

or,

"The product contains, or is derived from, material produced after 30 June 1998 of bovine, ovine or caprine animals which were tested and found negative for the presence of BSE using a test which was approved in accordance with Commission Decision [98/- - -/EC]".

Article 9

Member States may take further precautionary action in relation to animals slaughtered on their own territory.

Article 10

1. Member States or third countries may apply for derogations from the provisions of this Decision, in the light of their epidemiological status with respect to TSEs.

2. Member States or third countries wishing to apply for derogations as referred to in paragraph 1 shall submit to the Commission before 1 July 1998 an application, together with supporting documents, for recognition of their epidemiological status with respect to TSEs compiled in at least one of the official languages of the Community, in accordance with the provisions laid down in Annex I.

3. Without prejudice to Articles 11 and 12 (1), Member States which submit an application in accordance with paragraph 2 shall not be obliged to apply this Decision to animals which were born on and have never left their territory, or to animals born or reared on the territory of another country which has likewise submitted an application in accordance with paragraph 2.

4. Without prejudice to Article 11 (2) and Article 12 (2) and (3), third countries which submit an application in accordance with paragraph 2 shall not be obliged to apply Article 8.

5. The Commission shall communicate to the Member States, within the framework of the Standing Veterinary Committee, the names of the Member States or third countries which have applied for derogations as referred to in paragraph 1.

Article 11

1. The conditions which are to apply to Member States and third countries which have submitted an application in accordance with Article 10 shall be laid down by decision taken in accordance with the procedure laid down in Article 18 of Directive 89/662/EEC after consultation of the appropriate Scientific Committee and if necessary after Community inspections. .

2. The Commission shall take a Decision in accordance with paragraph 1 before 1 January 1999. Where such a Decision is not taken, the provisions of Articles 2 and 3 and, as appropriate, Article 8 (2) shall apply.

Article 12

1. Notwithstanding Articles 10 and 11, Member States in which native cases of BSE have occurred shall ensure that from 1 July 1998 at the latest, or, where the first native case of BSE occurs after 31 May 1998, no later than one month after official confirmation thereof, the brains, eyes spinal cord and distal ileum of bovine animals aged over 12 months are removed in accordance with the conditions laid down in Article 3 (1) and (2) from animals which died or were slaughtered on their territory and are destroyed in accordance with Article 4.

2. Notwithstanding Articles 10 and 11, in order to be imported into the Community after 30 June 1998, products of animal origin listed in Annex III which contain material derived from bovine animals produced after 30 June 1998 in third countries in which native cases of BSE have occurred, and are intended for human consumption or animal feed, must from 1 July 1998 at the latest, or where the first native case of BSE occurs after 31 May 1998, no later than one month after official confirmation thereof, be accompanied by the appropriate certificate, as required by Community legislation, supplemented by a declaration signed by the competent authority of the country of production, worded as follows:

"The product does not contain and is not derived from brains, eyes, spinal cord and distal ileum of bovine animals aged over 12 months as referred to in Commission Decision [98/- - -/EC] which were obtained after 30 June 1998 or mechanically recovered meat obtained from the vertebral column of bovine animals after 30 June 1998."

or,

"The product contains or is derived from material produced after 30 June 1998 of bovine animals which were tested and found negative for the presence of BSE using a test which was approved in accordance with Commission Decision [98/- - -/EC] ".

However, where the first native case of BSE occurs after 31 May 1998 the date referred to in the declaration may be replaced by a date no later than one month after official confirmation thereof.

3. Notwithstanding Articles 10 and 11, where animals coming from countries in which native cases of BSE have occurred are to be slaughtered after 30 June 1998 in the territory of Member States in which no native cases have occurred:

(a) – the Member State of destination shall ensure that the specified risk materials, or at least the risk materials referred to in paragraph 1, are removed from those animals and destroyed in accordance with Article 4. Those animals shall be slaughtered in slaughterhouses approved for that purpose by the competent authority and at the end of the normal slaughtering process.

(b) the Member State of dispatch shall ensure that:

(i) the animal health certificates are supplemented by the following words to be entered for bovine animals in the section "Health data concerning bovine animals" of the certificate referred to in Annex F to Council Directive 97/12/EC[22]:

'the animals listed below were born or reared ([1]) in a Member State or third country ([1]) in which native cases of BSE have occurred'; or,

([1]) Delete if not appropriate

for ovine and caprine animals at the request of the Member State of destination, in section V "Health information" of the certificates referred to in Annex E to Council Directive 91/68/EEC[23]:

'the animals listed below were born or reared ([1]) in a Member State or third country ([1]) in which native cases of BSE have occurred'.

([1]) Delete if not appropriate

(ii) the competent authority of the place of destination is informed of the nature of the bovine animals, or, at the request of the Member State of destination, of the nature of the ovine and caprine animals, in each consignment by means of a specifically coded ANIMO message or by fax;

[22] OJ No L 109, 25.4.1997, p.1.
[23] OJ No L 46, 19.2.1991, p.19.

(c) the third country of dispatch shall ensure that:

(i) the appropriate animal health certificates are supplemented by the following words, to be entered in the appropriate sections on health information for bovine animals:

'the animals listed below were born or reared ([1]) in a Member State or third country ([1]) in which native cases of BSE have occurred'; or,

([1]) Delete if not appropriate

for ovine and caprine animals at the request of the Member State of destination:

'the animals listed below were born or reared ([1]) in a Member State or third country ([1]) in which native cases of BSE have occurred'

([1]) Delete if not appropriate

(ii) the competent authority of the place of destination is informed of the nature of the bovine animals, or, at the request of the Member State of destination, of the nature of the ovine and caprine animals, in each consignment by fax.

Article 13

1. This Decision shall be without prejudice to the provisions of Decision 96/239/EC and Decision 94/474/EEC.

2. Decision 97/534/EC is hereby repealed and references to that Decision shall be construed as references to the present Decision.

Article 14

This Decision and the decisions referred to in Article 11 (1) shall be reviewed regularly in the light of new epidemiological information and scientific information with regard to criteria for determining the level of risk in specific regions and to the risk of exposure to TSEs resulting from infectivity in other animal species, age categories, tissues or materials. Where necessary, this Decision shall be amended in accordance with the procedure laid down in Article 18 of Directive 89/662/EEC after consultation of the appropriate Scientific Committee.

Article 15

This Decision shall apply from 1 April 1998. It does not apply to products as referred to in this Decision, containing or derived from specified risk materials produced before 1 July 1998.

Article 16

This Decision is addressed to the Member States.

Done at Brussels

For the Council

ANNEX I

Information to be submitted in support of an application for recognition of epidemiological status under article 10

All data must be provided on an annual basis and preferably from 1980 onwards, but at least from 1988.
Applicant States must make every effort to provide comprehensive and consistent information. Data which are not provided or are regarded as incomplete or as unsatisfactory may have to be replaced by worst case assumption for the purposes of a risk assessment.

Information must be provided on:

1. Structure and dynamics of the bovine, ovine and caprine animal populations

(a) absolute numbers of animals per species and breed, alive and at time of slaughter;
(b) age distributions of animals per species and breed, sex and type;
(c) age distribution of animals per species and breed, sex and type at time of slaughter;
(d) geographical distribution of the animals by species and breeds;
(e) geographical distribution of the animals by husbandry systems, herd sizes and production purposes;
(f) system of identification and capacities for tracing of animals.

2. Animal trade

(a) imports and exports;
(b) trade within the geographical area;
(c) imports of embryos and semen;
(d) use made of imported animals, embryos or semen;
(e) mechanisms used by slaughterhouses to identify animals and their origins, as well as data from these procedures.

3. Animal feed

(a) domestic production of Meat and Bone Meal (MBM), and its use per species and husbandry system (in particularly the proportion of the domestically produced MBM fed to bovine, ovine and caprine animals);
(b) imports of MBM, specifying country of origin, and its use per species and husbandry system (in particularly the proportion of that MBM fed to bovine, ovine and caprine animals);.
(c) exported MBM, specifying country of destination.

4. Meat and bone meal (MBM) bans

(a) complete description;
(b) dates of introduction;
(c) actual implementation, policing and compliance figures;
(d) possibilities of cross-contamination with other feed.

5. Specified bovine offal (SBO) and specified risk materials (SRM) bans

(a) complete description;
(b) dates of introduction;
(c) actual implementation, policing and compliance figures.

6. Surveillance of TSE, with particular reference to BSE and scrapie

(a) incidence of laboratory confirmed cases of BSE and scrapie;
(b) age distribution, geographical distribution, and countries of origin of cases;
(c) incidence of neurological disorders in which TSE could not be excluded on clinical grounds in any animal species;
(d) methodologies and programmes of surveillance and recording of clinical cases of BSE and scrapie, including awareness training for farmers, veterinarians, supervisory bodies and authorities;
(e) incentives for reporting cases, compensation and reward schemes;
(f) methodologies of laboratory confirmation and recording of suspect cases of BSE and scrapie;
(g) strains of BSE and scrapie agents possibly involved;
(h) existing systems or current plans for targeted active surveillance.

7. Rendering and feed processing

(a) all rendering and feed processing systems used;
(b) nature of the records of rendering and processing plants;
(c) quantitative and qualitative parameters of MBM and tallow production by each of the processing systems;
(d) the geographical areas from which the rendered materials originate;
(e) the type of raw material used;
(f) parameters on separate processing lines for materials from healthy and suspected animals;
(g) transport and storage systems for MBM or feed containing MBM.

8. BSE or scrapie related culling

(a) culling criteria;
(b) date of introduction of the culling scheme and of any subsequent modification;
(c) animals culled (details as specified in point 1);
(d) sizes of herds in which animals were culled.

ANNEX II

Use of specified risk materials for the production of medical devices

1. Specified risk material must not be used for the manufacture of active implantable medical devices within the meaning of Directive 90/385/EEC and of medical devices within the meaning of Directive 93/42/EEC which are intended to come in direct contact with patients, unless the use of such material is authorized in accordance with this Decision.

2. Without prejudice to point 1 and unless the use of specified risk material is authorized in accordance with this Decision:

   (a) tallow derivatives may be used provided that they are produced following an appropriate, documented and validated method such as :

   - transesterification or hydrolysis at not less than 200°C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production);

   - saponification with NaOH 12 M :
     - batch process : at not less than 95°C for not less than 3 hours,
     - continuous process : at not less than 140°C for not less than 8 minutes under pressure or equivalent.;

   (b) materials of bovine, ovine or caprine origin which may be derived from specified risk material may be used until 30 September 1999 as reagents or where they are only indirectly associated with the manufacturing process or disappear from that manufacturing process, unless there are no adequate alternatives;

(c) intestinal material of bovine, ovine or caprine origin may be used for the production of sutures provided that:

- that raw material is sourced from countries where there is reliable evidence that no native cases of BSE have occurred,
- sourcing is subject to veterinary control and inspection,
- that raw material used originated from animals certified by a veterinarian as being fit for human consumption,
- evidence on safety of sourcing, including health attestations is retained by the manufacturer and
- all relevant production processes are carried out in accordance with legal requirements so as to provide optimal security;

(d) materials of bovine, ovine or caprine origin which may be derived from specific risk material may be used until 31 March 2000 at the latest in the production of medical devices, for which and for so long as there are no satisfactory alternatives.

3. Where materials of bovine, ovine or caprine origin are used, a risk assessment must be performed which addresses all relevant aspects, including those in relation to the sourcing, nature and quantities of animal material used, production processes and conditions of use of finished devices. The above mentioned procedure shall be documented.

4. Compliance with the provisions this Annex must be verified in the framework of application of the procedures laid down in Directives 90/385/EEC and 93/42/EEC.

5. Without prejudice to Article 15, the provisions of this Annex must apply to medical devices manufactured, , after 31 March 1999 at the latest.

ANNEX III

(Products referred to in Article 6 (2), Article 8 (2) and Article 12 (2))

(a) 'Fresh meat', as defined by Council Directive 64/433/EEC[1];

(b) 'Minced meat' and 'meat preparations', as defined by Council Directive 94/65/EC[2];

(c) 'Meat products' and 'other products of animal origin', as defined by Council Directive 77/99/EEC[3];

(d) 'Milk products', as defined by Council Directive 92/46/EEC[4], which are destined for human consumption and containing gelatin or tallow;

(e) 'Milk products', as defined by Council Directive 92/118/EEC, which are destined for animal consumption and containing gelatin or tallow;

(f) 'Fishery products', as defined by Council Directive 91/493/EEC[5], which are destined for human consumption and containing gelatin or tallow;

(g) 'Egg products', as defined by Council Directive 89/437/EEC[6], which are destined for human consumption and containing gelatin or tallow;

(h) 'Snails or frogs' legs', as referred to in Council Directive 92/118/EEC, which are destined for human consumption and containing gelatin or tallow;

(i) 'Rendered fats', as referred to by Council Directive 92/118/EEC;

(j) 'Gelatin', as referred to in Council Directive 92/118/EEC;

(k) 'Petfood', as referred to in Council Directive 92/118/EEC;

(l) 'Processed animal protein', as referred to in Council Directive 92/118/EEC;

(m) 'Bones' and 'bone products', as referred to in Council Directive 92/118/EEC;

(n) 'Raw material for the manufacture of animal feedingstuffs', as referred to in Council Directive 92/118/EEC.

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[1] OJ No L 121, 29.7.1964, p. 2012/64.
[2] OJ No L 368, 31.12.1994, p. 10.
[3] OJ No L 26, 31.1.1977, p.85.
[4] OJ No L 268, 14.9.1992, p. 1.
[5] OJ No L 268, 24.9.1991, p. 15.
[6] OJ No L 212, 22.7.1989, p. 87.

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